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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,569	07/11/2003	Robin A. Robinson	NOVV-003/00US	5752
58349 7590 03/12/2008 COOLEY GODWARD KRONISH LLP ATTN: Patent Group Suite 1100 777 - 6th Street, NW WASHINGTON, DC 20001				
EXAMINER				
HILL, MYRON G				
ART UNIT		PAPER NUMBER		
1648				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/617,569

Applicant(s)

ROBINSON ET AL.

Examiner

MYRON G. HILL

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/17/07 has been entered.

Claims 34-63 are under consideration.

Rejection Necessitated By Amendment

Claim Rejections - 35 USC § 103

Claims 34-42, and 45-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* (J of Virology Vol 75, pages 6154-6165, from IDS) and Saito *et al.* (Vaccine 2001 Vol. 20 pages 125-133).

Applicant argues the following:

that the examiner has made an improper obvious type rejection because of the use of inherency as part of the obviousness rejection and requests the examiner to point out case law that supports such analysis or drop the argument,

that the examiner has not provided evidence supporting his assertions of the activity in the prior art, lacking evidence, the rejection should be withdrawn,

that there is no guarantee that the particles have the enzymatic activity citing MPEP 2112,

that the scientific and legal analysis of the examiners assertions have no scientific basis, and

that applicant submits a declaration by Smith of unexpected results.

Applicant's arguments have been fully considered and not found persuasive.

The Federal Circuit affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references, see **In re Napier, 34 USPQ2d 1782 (Fed. Cir. 1995)**.

The examiner has discussed the teachings in Latham et al., and put forth sound scientific reasoning based on the teaching in the prior art and the similarity to the products made in the specification in the previous actions. Applicant argues that antibody binding on blots or fixed cells does not show that proteins have its natural state activity. Latham et al. also show EM results and explain the similarities in the structure of the VLPs they made to wild type influenza particles. Also, applicant argues that there is no scientific basis for the assertion by the examiner that the VLPs have the activity as claimed. For this aspect of the argument, the examiner has argued that the particles are similar to wildtype as discussed in Latham et al., and that the VLPs are made in the same manner, both the prior art and the specification use baculovirus to express the influenza proteins.

The scientific and legal points have been discussed above.

As far as MPEP 2100 is concerned as applicant argues 2112, as noted above inherency can be used in a 103 rejection and according to MPEP 2112 V.:

ONCE A REFERENCE TEACHING PRODUCT APPEARING TO BE
SUBSTANTIALLY IDENTICAL IS MADE THE BASIS OF A REJECTION,
AND THE EXAMINER PRESENTS EVIDENCE OR REASONING
TENDING TO SHOW INHERENCY, THE BURDEN SHIFTS TO THE
APPLICANT TO SHOW AN UNOBVIOUS DIFFERENCE

"[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency' under 35 U.S.C. 102, on prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

The burden has been shifted to applicant to show that the product made would not have the functional properties. Applicant argues that the references fail to teach the enzymatic activity. The structure made in the obviousness rejection is the same as claimed. While different types of influenza are "different", the use of different influenzas in the method of Latham et al. to make a VLP is the substitution of equivalents in that avian influenza is influenza and the proteins are similar. Applicant's arguments assert that the prior art does not have disclose the enzymatic activity. The similarities have been pointed out between the influenza virus and the VLP made in the prior art and the office has noted that the products (103 made product and the claimed product) are made by the same method. Applicant has only argued that Latham et al. show fixed VLPs and they would not have activity. The fixed VLPs are used to demonstrate that the

VLPs are like viral particles as taught in Latham et al. It is well known in the art that influenza virus/proteins have HA and NA activity.

In response to applicant's arguments concerning the unmentioned enzymatic activity in Latham et al., Matassov et al. (Viral Immunology, September 1, 2007, 20(3): 441-452) is cited as evidence that influenza VLPs have enzymatic activity as seen in Figure 2. Figure 2 shows VLPs that have hemmagglutination and neuraminidase activity.

The declaration of Smith has been considered and not found persuasive for reasons as follows:

The declaration is not persuasive as to the asserted lack of functional properties of the prior art VLPs because it does not show that VLPs made by the method used in the prior art do not have the recited functional properties. There is no objective evidence that there would not be success in making the VLP. The declaration shows a difference in level of product made, not that the VLP could not be made.

The declaration is not persuasive as to the asserted unexpected result because efficiency is not a consideration. The claim is drawn a product. If the prior art was unable to be made VLP, then it would have been unexpected to be able to make a VLP with avian influenza virus proteins.

It is possible that if the vaccine made by this method produced a more immunogenic and protective vaccine compared to other VLPs, then it would be an unexpected result that it made a better vaccine.

Matassov et al. is added to the rejection to show that influenza VLPs made in baculovirus have enzymatic activity (Figure 2).

The newly added claims are rejected over the same references for the same reasons as previously made for claims 34-42, and 45-55 in this 35 USC § 103 rejection because the claims are written in comprising language and thus open to additional elements, avian influenza M1, HA, and NA and thus they are of the similar scope and limitations as 34-42, and 45-55.

Thus, the claims are *prima facie* obvious over Latham *et al.* and Saito *et al.*

Rejection Maintained

Claims 34, and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Latham *et al.* and Saito *et al.* as discussed above and Gupta *et al.* (Vaccine 2001 Vol. 14 pages 219-225).

Applicant argues that the cited references do not teach all the claimed elements.

Applicant's arguments have been fully considered and not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant does not mention Saito *et al.* in the response. It is not clear if applicant considered all the references.

As far as the claim limitation of enzymatic activity, it is discussed below and applicant has not differentiated the product made in the rejection versus the claimed product.

In response to applicant's arguments concerning the unmentioned enzymatic activity in Latham et al., Matassov et al. (Viral Immunology, September 1, 2007, 20(3): 441-452) is cited as evidence that influenza VLPs have enzymatic activity as seen in Figure 2. Figure 2 shows VLPs that have hemmagglutination and neuraminidase activity.

The rejection is maintained.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on 5:30 am-2 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/M. G. H./
Examiner, Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648